UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

May 30, 2019

MEMORANDUM

Subject: Efficacy Review for White; EPA Reg. No. 777-128; DP Barcode: D451040; Submission #: 1031121; E-Sub # 36356.

From: Ibrahim Laniyan, Ph.D.
Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah L. Blackburn, PhD, MPH.
Senior Scientist
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: 6/11/19

To: Eric Miederhoff RM31 / Emilia Oiguenblik
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Formulation from the Label:

Active Ingredients	% by wt.
Alkyl dimethyl benzyl ammonium saccharinate ……..	0.960 %
Octyl decyl dimethyl ammonium chloride ……	0.720 %
Dioctyl dimethyl ammonium chloride ……...	0.288 %
Didecyl dimethyl ammonium chloride ……..	0.432 %
Other Ingredients: …….....	97.600 %
Total	100.000 %

I. BACKGROUND

Product Description (as packaged, as applied): Concentrate liquid.

Submission type: Amendment

Currently registered efficacy claim(s): Laundry Sanitizer

Requested action(s): • Addition of various microorganisms for disinfection on soft surfaces
• Addition of marketing claims to the master text label
• Alternate brand names

Documents considered in this review:

- Letter from applicant to EPA dated February 08, 2019
- Application for Pesticide (EPA form 8570-1) dated February 08, 2019
- Confidential Statement of Formula (EPA form 8570-4) dated February 08, 2019
- Formulator's Exemption Statement (EPA form 8570-27) dated February 08, 2019
- Certification with Respect to Citation of Data (EPA Form 8570-34) dated February 08, 2019
- Data Matrix (EPA Form 8570-35) dated February 08, 2019
- 7 efficacy studies (MRID nos. 507729-01 – 507729-07)
- Proposed label dated February 8, 2018.

Note: Tested product Project Mac & Cheese - GLP-Efficacy Testing, e0042-196, is identified as "White"

II. PROPOSED DIRECTIONS FOR USE

(For) Single Dose (use) (for) (all washing machine (types)(styles)):
Add (full) contents of (pack)(package)(sachet) to your fabric softener (drawer)(compartment) or directly to the rinse cycle.

For (Standard)(Top Load) Machine(s):
Add (150 mL) ((X) capful(s)) (each filled to (level)(line) (X) of the dosing (cup)(cap)) to the fabric softener (compartment)(drawer) (of the washing machine) or directly to your rinse cycle wash.

For (High Efficiency)(HE)(Front Load) Machine(s):
Add (100 mL) ((X) capful(s) each filled to (level)(line)(X) of the dosing (cup)(cap)) to the fabric softener (compartment)(drawer) (of the washing machine) or directly to your rinse cycle wash. (If total amount does not fit, add the remaining amount into the (compartment)(drawer) when rinse cycle wash begins.)

To Sanitize: add to rinse cycle and leave product in (contact)(rinse cycle) for 16 minutes.

To Disinfect: add to rinse cycle and leave product in (contact)(rinse cycle) for 15 minutes. Rinse thoroughly with clean water or wash as directed.

III. STUDY SUMMARIES

1.	**MRID**	507729-01	**Study Completion Date:**	December 10, 2018 January 22 and 31, 2019
Study Objective		Disinfectant – Virucidal		

Testing Lab, Lab Study ID		Accuratus Lab Services, A26412					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		2009-H1N1 Influenza A virus (Novel H1N1), Strain A/Mexico/4108/2009, CDC #2009712192; Obtained from the Centers for Disease Control and Prevention (CDC), Atlanta, GA					
Indicator Cell Culture		MDCK (canine Kidney) cells (ATCC CCL-34)					
Test Method		Accuratus Protocol # REK01091018.FLUA (Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces) (*copy provided*)					
Application Method		Carriers were individually exposed to a 2.00 ml aliquot of the use dilution					
Test Substance Preparation	**Name/ID**	Project Mac & Cheese - GLP-Efficacy Testing, e0042-196					
	Lots **☐ 1 ☒ 2 ☐ 3**	Batch 2250-08 and Batch 2250-09					
	Preparation	Dilution 1:28 defined as 7.14 ml of test substance + 192.86 ml of 400 ppm AOAC Synthetic Hard Water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		one dried virus film per batch					
Test conditions		**Contact time**	5 minutes	**Temp**	21.0°C	**RH**	
Neutralizer		Sephadex LH-20 gel filtration column					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carrier inoculated with 0.2 ml, uniformly, over the bottoms of twenty separate 100X15mm sterile glass petri dishes. The virus films were dried at 21.0°C in a relative humidity of 25.07% until visibly dry (20 minutes).					

2.	**MRID**	507729-02	**Study Completion Date:**	December 5, 2018 January 22 and 31, 2019
Study Objective		Disinfectant – Virucidal		
Testing Lab, Lab Study ID		Accuratus Lab Services, A26411		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Avian Influenza A (H3N2) Reassortant virus, Strain A/Washington/897/80 x A/Mallard/New York/6750/78 (ATCC VR-2072)		
Indicator Cell Culture		MDCK (canine Kidney) cells (ATCC CCL-34)		
Test Method		Accuratus Protocol # REK01091018.AFLU (Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces) (*copy provided*)		
Application Method		Carriers were individually exposed to a 2.00 ml aliquot of the use dilution		
Test Substance Preparation	**Name/ID**	Project Mac & Cheese - GLP-Efficacy Testing, e0042-196		
	Lots **☐ 1 ☒ 2 ☐ 3**	Batch 2250-08 and Batch 2250-09		
	Preparation	Dilution 1:28 defined as 7.14 ml of test substance + 192.86 ml of 400 ppm AOAC Synthetic Hard Water		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		one dried virus film per batch		
Test conditions		**Contact time**	5 minutes	**Temp** 20.0°C **RH**
Neutralizer		Sephadex LH-20 gel filtration column		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carrier inoculated with 0.2 ml, uniformly, over the bottoms of twenty separate 100X15mm sterile glass petri dishes. The virus films were dried at 20.0°C in a relative humidity of 40% until visibly dry (20 minutes).		

3.	**MRID**	507729-03	**Study Completion Date:**	December 10, 2018 January 22 and 31, 2019
Study Objective		Disinfectant – Virucidal		
Testing Lab, Lab Study ID		Accuratus Lab Services, A26410		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Influenza B virus, Strain B/Hong Kong/5/72 (ATCC VR-823)		
Indicator Cell Culture		MDCK (canine Kidney) cells (ATCC CCL-34)		

Test Method		Accuratus Protocol # REK01091018.FLUB (Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces) (*copy provided*)					
Application Method		Carriers were individually exposed to a 2.00 ml aliquot of the use dilution					
Test Substance Preparation	**Name/ID**	Project Mac & Cheese - GLP-Efficacy Testing, e0042-196					
	Lots ☐ 1 ☒ 2 ☐ 3	Batch 2250-08 and Batch 2250-09					
	Preparation	Dilution 1:28 defined as 7.14 ml of test substance + 192.86 ml of 400 ppm AOAC Synthetic Hard Water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		one dried virus film per batch					
Test conditions		**Contact time**	5 minutes	**Temp**	20.0°C	**RH**	
Neutralizer		Sephadex LH-20 gel filtration column					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carrier inoculated with 0.2 ml, uniformly, over the bottoms of twenty separate 100X15mm sterile glass petri dishes. The virus films were dried at 20.0°c in a relative humidity of 40% until visibly dry (20 minutes).					

4.	**MRID**	507729-04	**Study Completion Date:**		December 5, 2018 January 22 and 31, 2019		
Study Objective		Disinfectant – Virucidal					
Testing Lab, Lab Study ID		Accuratus Lab Services, A26408					
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Human Coronavirus, Strain 229E (ATCC VR-740)					
Indicator Cell Culture		Wl-38 (human lung) cells (ATCC CCL-75)					
Test Method		Accuratus Protocol # REK01091018.COR (Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces) (*copy provided*)					
Application Method		Carriers were individually exposed to a 2.00 ml aliquot of the use dilution					
Test Substance Preparation	**Name/ID**	Project Mac & Cheese - GLP-Efficacy Testing, e0042-196					
	Lots ☐ 1 ☒ 2 ☐ 3	Batch 2250-08 and Batch 2250-09					
	Preparation	Dilution 1:28 defined as 7.14 ml of test substance + 192.86 ml of 400 ppm AOAC Synthetic Hard Water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		One dried virus film per batch					
Test conditions		**Contact time**	5 minutes	**Temp**	20.0°C	**RH**	
Neutralizer		Sephadex LH-20 gel filtration column					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carrier inoculated with 0.2 ml, uniformly, over the bottoms of twenty separate 100X15mm sterile glass petri dishes. The virus films were dried at 20.0°C in a relative humidity of 50% until visibly dry (20 minutes).					

5.	**MRID**	507729-05	**Study Completion Date:**	December 5, 2018 January 22 and 31, 2019	
Study Objective		Disinfectant – Virucidal			
Testing Lab, Lab Study ID		Accuratus Lab Services, A26409			
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Respiratory syncytial virus, Strain Long (ATCC VR-26)			
Indicator Cell Culture		Hep-2 (human larynx carcinoma) cells (ATCC CCL-23)			
Test Method		Accuratus Protocol # REK01091018.RSV (Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces) (*copy provided*)			
Application Method		Carriers were individually exposed to a 2.00 ml aliquot of the use dilution			
	Name/ID	Project Mac & Cheese - GLP-Efficacy Testing, e0042-196			

Test Substance Preparation	**Lots** ☐ **1** ☒ **2** ☐ **3**	Batch 2250-08 and Batch 2250-09					
	Preparation	Dilution 1:28 defined as 7.14 ml of test substance + 192.86 ml of 400 ppm AOAC Synthetic Hard Water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		One dried virus film per batch					
Test conditions		**Contact time**	5 minutes	**Temp**	20.0°C	**RH**	
Neutralizer		Sephadex LH-20 gel filtration column					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carrier inoculated with 0.2 ml, uniformly, over the bottoms of twenty separate 100X15mm sterile glass petri dishes. The virus films were dried at 20.0°C in a relative humidity of 50% until visibly dry (20 minutes).					

6.	**MRID**	507729-06	**Study Completion Date:**	January 17 and 31, 2019			
Study Objective		Disinfectant – Bactericidal					
Testing Lab, Lab Study ID		Accuratus Lab Services, A26439					
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Staphylococcus aureus (ATCC 6538)*					
Test Method		ACCURATUS Protocol # REK01092518.UD.2 (AOAC Use Dilution Method) (*copy provided*)					
Application Method		Carriers were individually exposed to a 10.0 ml aliquot of the use dilution					
Test Substance Preparation	**Name/ID**	Project Mac & Cheese - GLP-Efficacy Testing, e0042-196					
	Lots ☐ **1** ☐ **2** ☒ **3**	Batch 2250-08, Batch 2250-09, and Batch 2250-10					
	Preparation	Dilution 1:28 defined as 7.14 ml of test substance + 192.86 ml of 400 ppm AOAC Synthetic Hard Water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Stainless Steel Penicylinders, 60 per batch					
Test conditions		**Contact time**	15 minutes	**Temp**	20.0°C	**RH**	-
Neutralizer		Letheen Broth + 0.07% Lecithin + 0.5% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carriers were immersed for 15 min at a rate of 1 carrier per 1 ml culture; and dried for 38 minutes at 35.9-36.3°C and at a 48.2-60.2% relative humidity.					

7.	**MRID**	507729-07	**Study Completion Date:**	January 17 and 31, 2019			
Study Objective		Disinfectant – Bactericidal					
Testing Lab, Lab Study ID		Accuratus Lab Services, A26438					
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Pseudomonas aeruginosa (ATCC 15442)*					
Test Method		ACCURATUS Protocol # REK01092518.UD.1 (AOAC Use Dilution Method) (*copy provided*)					
Application Method		Carriers were individually exposed to a 10.0 ml aliquot of the use dilution					
Test Substance Preparation	**Name/ID**	Project Mac & Cheese - GLP-Efficacy Testing, e0042-196					
	Lots ☐ **1** ☐ **2** ☒ **3**	Batch 2250-08, Batch 2250-09, and Batch 2250-10					
	Preparation	Dilution 1:28 defined as 7.14 ml of test substance + 192.86 ml of 400 ppm AOAC Synthetic Hard Water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Stainless Steel Penicylinders,, 60 per batch					
Test conditions		**Contact time**	15 minutes	**Temp**	20°C	**RH**	-
Neutralizer		Letheen Broth + 0.07% Lecithin + 0.5% Tween 80					
Reviewer comments		Carriers were immersed for 15 min at a rate of 1 carrier per 1 ml culture; and dried for 38 minutes at 36.0-36.3°C and at a 48.0-63.2% relative humidity.					

(i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	

V. RESULTS

MRID	Organism	Description	Results		Dried Virus Control ($TCID_{50}$/Carrier)
			Batch 2250-08	Batch 2250-09	
5 minutes, 1:28 dilution, 5% soil load					
507729-01	2009-H1N1 Influenza A Virus (Novel H1N1)	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{6.80}$
		10^{-2} to 10^{-7} dilution	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1ml	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
		$TCID_{50}$/carrier	$\leq 10^{1.80}$	$\leq 10^{1.80}$	
		Log Reduction	≥5.00		
507729-02	Avian Influenza A (H3N2) Reassortant virus, Strain A/Washington/897/80 x A/Mallard/New York/6750/78 (ATCC VR-2072)	10^{-1} dilution	Complete Inactivation	Cytotoxicity	$10^{6.55}$
		10^{-2} to 10^{-6} dilution	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1ml	$\leq 10^{0.50}$	$\leq 10^{1.50}$	
		$TCID_{50}$/carrier	$\leq 10^{0.80}$	$\leq 10^{1.80}$	
		Log Reduction	≥5.75	≥4.75	
507729-03	Influenza B virus, Strain B/Hong Kong/5/72 (ATCC VR-823)	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{4.80}$
		10^{-2} to 10^{-6} dilution	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1ml	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
		$TCID_{50}$/carrier	$\leq 10^{1.80}$	$\leq 10^{1.80}$	
		Log Reduction	≥3.00		
507729-04	Human Coronavirus, Strain 229E (ATCC VR-740)	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{6.30}$
		10^{-2} to 10^{-6} dilution	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1ml	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
		$TCID_{50}$/carrier	$\leq 10^{1.80}$	$\leq 10^{1.80}$	
		Log Reduction	≥4.50		
507729-05	Respiratory syncytial virus, Strain Long (ATCC VR-26)	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{4.80}$
		10^{-2} to 10^{-6} dilution	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1ml	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
		$TCID_{50}$/carrier	$\leq 10^{1.80}$	$\leq 10^{1.80}$	
		Log Reduction	≥3.00		

MRID (Test Date)	Organism	No. Exhibiting Growth/Total No. Tested			Average log_{10}/Carrier
		Batch 2250-08	Batch 2250-09	Batch 2250-10	
1:28 dilution, 5% soil load - 15 minutes contact time					
507729-06	*Staphylococcus aureus* (ATCC 6538)	1/60	1/60	0/60	6.44/6.48/6.81
507729-07	*Pseudomonas aeruginosa* (ATCC 15442)	0/60	0/60	0/60	5.52

VI. CONCLUSIONS

For laundry disinfection, the Agency recommends a simulated-use study using the American Society for Testing and Materials (ASTM) Standard Test Method for Evaluation of Laundry Sanitizers and Disinfectants (E 2274) or Standard Test Method for Evaluation of Laundry Sanitizers and Disinfectants for Use in High Efficiency Washing Operations (E 2406). Alternatively, an actual in-use study utilizing washing machines may be used.

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
507729-06 and 507729-07	Laundry Bactericidal Disinfectant	Hard, non-porous surfaces	Use Dilution 1:28	15 minutes	5%	400 ppm Hard Water	*Staphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 15442)	**No**
507729-01 – 507729-05	Laundry Virucidal Disinfectant	Hard, non-porous surfaces	Use Dilution 1:28	5 minutes	5%	400 ppm AOAC Synthetic Hard Water	2009-H1N1 Influenza A Virus (Novel H1 N1) Avian Influenza A (H3N2) Reassortant virus, Strain A/Washington/897/80 x A/Mallard/New York/6750/78 (ATCC VR-2072) Influenza B virus, Strain B/Hong Kong/5/72 (ATCC VR-823) Human Coronavirus, Strain 229E (ATCC VR-740) Respiratory syncytial virus, Strain Long (ATCC VR-26)	**No**

The submitted data only support "Laundry Disinfecting pre-soak treatments".

VII. LABEL COMMENTS

Proposed Label dated February 8, 2018

1. The proposed label claims that the product, White (EPA Reg. No. 777-128), is an effective laundry bacterial disinfectant, when used at 1:28 dilution during rinse cycle for 15 minutes contact time; **are not acceptable. All bacterial disinfection claims must be removed.**

2. The proposed label claims that the product, White (EPA Reg. No. 777-128), is an effective laundry virucidal disinfectant, when used at 1:28 dilution during rinse cycle for 5 minutes contact time; **are not acceptable**. **All virucidal disinfection claims must be removed.**

3. Registrant must make the following changes to the proposed label:

- All disinfection claims must be removed from the label.
- On pages 8 and 9, address the terms "Eliminate" must be removed from sanitization and claims because it is synonym of sterilize.

- On page 8, change the phrase “Kills 99.9% of bacteria*** to stop the transmission from (clothing to clothing) (garment to garment) in the same (wash)(load)”, to read “Kills 99.9% of bacteria*** **to reduce the spread of organisms from** (clothing to clothing) (garment to garment) in the same (wash)(load)”.
- On page 9, change the phrase “Helps stops the spread of germs** through your laundry”, to read “Helps **reduce** the spread of germs** through your **treated** laundry”.
- On page 9, remove the phrase “Kills 99.9% of (bacteria)(germs)** to stop the transmission from (clothing to clothing) (garment to garment) in the same (wash)(load)”, as it implies transmission control of organisms.